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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,338	02/20/2001	Franz Paul Armbruster	0756-0118P	9282

2292 7590 05/28/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/28/2003

46

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,338

Applicant(s)

ARMBRUSTER, FRANZ PAUL

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 16-20, 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 15 and 21-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claim 15 under 35 USC 112, second paragraph is maintained.

Applicant argues that support for the claim is found on page 6, lines 3-9.

Applicant's argument was considered but not persuasive for the following reason.

The instant claim recites, "tyrosine, FITC substituted tyrosine" however, the present specification recites "tyrosine, substituted tyrosine" and "FITC" (see page 6, lines 6-7). Therefore, the present specification lacks support for the recitation of "FITC substituted tyrosine" as recited by the instant claim. Correction is requested.

For this reason and those given in previous Office Actions, the rejection of claim 15 under 35 USC 112, second paragraph is maintained.

3. The rejection of claims 21-24 under 35 USC 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 102

4. The rejection of claims 21-24 under 35 USC 102(b) over Holick (WO 97/24127) is maintained.

Applicant argues (a) the "biotin conjugate" shown on page 17 of the reference is not biotin; (b) the chemical formula shown in figure 6 of Holick is an ester; (c) the data present in Holick merely shows that there was a vitamin D ring system present in its disclosure but there is no proof that the 25 OH group was present in any one of the target compounds; and (d) the requirement by Holick of an eleven-fold surplus of biotinylated target compound to replace one molecule of 25-OH vitamin D on the vitamin D binding protein is proof that the reference utilized biotinylated vitamin D instead of biotinylated 25 OH vitamin D. Applicant's argument was considered but not persuasive for the following reasons.

Based on the teachings of the reference, especially the chemical formula shown in figure 6 of Holick, it would be obvious to the skilled artisan in the art that the structure of biotin shown on page 17 of the reference is an obvious error. It is the examiner's position that the structure shown of page 17 of the reference comprising the right structural depiction of biotin falls within the claimed compound and, thus, applicant's argument that the reference does not teach utilization of the claimed compound is not persuasive.

In response to applicant's argument that there is no proof that the 25 OH group was present in any one of the target compounds, it is noted that the reference teaches that said assay is useful in detecting 1,25(OH)₂-vitamin D as well as 25-OH-vitamin D.

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(see the entire article, especially page 5, lines 12-14; page 7, lines 11-13; pages 18-21, Example 7; Figure 4). The data of Holick shown in figure 4 is evidence of the presence of 25-OH-vitamine D.

Lastly, applicant argues the amount of compound utilized by the reference is evidence that biotinylated vitamin D and not biotinylated 25-OH-vitamin D compounds were utilized in the assay taught by Holick. However, as stated above, based on the teachings of the reference it would be obvious to the skilled artisan that biotinylated 25-OH vitamin D compounds were made and utilized in the assay taught by Holick (see especially Example 7A and B). The examiner does not agree that the amount of the compound utilized by the reference is evidence that compounds utilized by Holick is not a biotinylated 25-OH vitamin D compound. In addition, the instant claims are not limited to specific amounts and, thus, applicant's argument is not persuasive.

In summary, based on the teachings of the cited prior art, the utilization of biotinylated 25-OH-vitamin D compounds in assaying for 1,25(OH)₂-vitamin D and 25-OH-vitamin D would have been obvious to the skilled artisan in the art at the time of the present application.

For these reasons and those given in previous Office Actions, the rejection of claims 21-24 under 35 USC 102(b) over Holick (WO 97/24127) is maintained.

Allowable Subject Matter

5. Claims 14, 16-20, 25 and 26 are allowed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

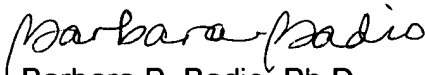
Telephone Inquiry

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
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BB
May 27, 2003